



Researcher Training Conference

Inventories, Records and Reports

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LEGAL DISCLAIMER

The following presentation was accompanied by an oral presentation on **February 6, 2019**, and does not purport to establish legal standards that are not contained in statutes, regulations, or other competent law.

Statements contained in this presentation that are not embodied in the law are not binding on DEA.

Summaries of statutory and regulatory provisions that are summarized in this presentation do not purport to state the full extent of the statutory and regulatory requirements of the cited statutes and regulations. **I have no financial relationships to disclose.**



Course Objectives

- § **Discuss who is responsible for maintaining controlled substance records.**
- § **General recordkeeping requirements.**
- § **Basic inventory requirements.**
- § **Required records of receipt and distribution.**
- § **Determine when and what reports are required to be submitted.**





Who Must Keep Records

§ **Every registrant...shall maintain the records and inventories and shall file the reports required...**

21 C.F.R. § 1304.03(a)



Responsible Party

21 CFR § 1304.03(a)

The DEA **registrant** is the person who is responsible for keeping controlled substance records.

- § Not your office manager
- § Not your lab assistant
- § Not your vendor
- § Not your employer/university



General Recordkeeping



General Record Keeping Requirements

Requirements that apply to all controlled substance records required to be kept:

- § **Must be complete and accurate.**
21 C.F.R. § 1304.21(a)
- § **Must be stored at the registered location.**
21 C.F.R. § 1304.21(b)
- § **Must be kept for two years.**
21 C.F.R. § 1304.04(a)



General Record Keeping Requirements

§ **Must be readily retrievable.**

21 C.F.R. § 1304.04(f)(2)

§ **Records must be kept for each separate DEA registered activity.**

21 C.F.R. § 1304.21(c)

§ **Must be kept for each DEA registered location.**

21 C.F.R. § 1304.21(b)



Inventories



Inventory Requirements

§ Is a “Physical Count”

§ Exact count for CI & CII or measure of the contents.

§ Estimate count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case you must make an exact count of the contents.

§ Must include all controlled substances “On Hand” (In possession/under the control of).

§ [\(21 C.F.R. §1304.11\(a\)\)](#)



Inventory Requirements

§ **Inventory date must reflect the date of the actual inventory.**

§ **Maintained in Written, Typewritten, or Printed Form at the Registered Location.**

21 C.F.R. § 1304.11(a)



Separate Inventories

§ **Separate inventories are required for each registered location.**

21 C.F.R. § 1304.11(a)

§ **Must be taken at the Beginning of Business (BOB) or Close of Business (COB).**

21 C.F.R. § 1304.11(a)

§ **Separate inventories for each independent activity.**

21 C.F.R. § 1304.11(a)



Initial Inventories

- § **Inventory of all stocks of controlled substances.**
- § **On the date you first engage in the manufacture, distribution, or dispensing of controlled substances.**
21 C.F.R. § 1304.11(a)
- § **Best if labeled “Initial Inventory.”**
- § **If nothing on hand record “0.”**



Biennial Inventories

§ **The biennial inventory is required to be taken on any date within two years of a previous required inventory.**

21 C.F.R. § 1304.11(c)

§ **Best if labeled “Biennial Inventory.”**

§ **If nothing on hand record “0.”**



Newly Scheduled Controlled Substances

- § **When a controlled substance is newly scheduled or rescheduled a physical inventory must be taken immediately.**
- § **Must be taken at the Beginning of Business or Close of Business.**



Records



Separate Schedule I & II Records

§ Schedule I & II controlled substance records shall be maintained separately from all other records.

21 C.F.R. § 1304.04(f)(1)



Separate Schedule III-V Records

§ **Records of schedules III-V controlled substances must be kept separate from all other records or readily retrievable.**

§ **Records that are readily retrievable can be separated out in a reasonable time.**

[21 C.F.R. § 1300.03](#)



Separate Schedule III-V Records

§ **Some examples of ways to render your records readily retrievable include but not limited to:**

21 C.F.R. § 1300.01

§ **Items are asterisk**

§ **Redlined**

§ **Or in some manner which sets them visually apart.**



DEA Form 222

- § **The DEA Form 222 is used for the acquisition and distribution of schedule I & II controlled substances.**
- § **The DEA Form 222 must be filled out completely and accurately.**
- § **The signer of the DEA application or renewal is the individual authorized to execute (sign) DEA Form 222's.**



Power Of Attorney

Anyone else who wishes to execute a DEA Form 222 must first obtain authorization through Power of Attorney from the signer of the DEA application or renewal.

See Reverse of PURCHASER'S
Copy for Instructions

No order form may be issued for Schedule I and II substances unless a
completed application form has been received. (21 CFR 1305.04)

OMB APPROVAL
No. 1117-0010

TO: (Name of Supplier)

STREET ADDRESS

CITY and STATE

DATE

TO BE FILLED IN BY SUPPLIER

SUPPLIER'S DEA REGISTRATION No.

LINE No.	TO BE FILLED IN BY PURCHASER					
	No. of Packages	Size of Package	Name of Item	National Drug Code	Packages Shipped	Date Shipped
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						

LAST LINE
COMPLETED

(MUST BE 10 OR LESS)

SIGNATURE OF PURCHASER
OR ATTORNEY OR AGENT

Date Issued

20010101

DEA Registration No.

DEAREGNO

Name and Address of Registrant

VOID VOID VOID
VOID VOID VOID
VOID VOID VOID
VOID VOID VOID

Schedules

XXXXXXXXXXXXXX

Registered as a

XXXXXXXXXXXXXX

No. of this Order Form

00000007

DEA Form -222
(Oct. 2004)

U.S. OFFICIAL ORDER FORMS - SCHEDULES I & II
DRUG ENFORCEMENT ADMINISTRATION

111381999



Purchase Records CIII-CV

- § **Must immediately inventory all schedule III-V controlled substances when received.**
- § **Annotate the date received on the record of receipt.**



Dispensing Log/Research Subject

Dispensing of controlled substances can be entered in a research subject's chart or can be maintain in a dispensing log with the below information:

21 C.F.R. § 1304.22(c)

- § Actual Name of Controlled Substance, Form, Quantity, Strength;
- § Number of Units or Volume of Finished Form Dispensed;
- § Name, Address of the Person to Whom It Was Dispensed;
- § Date of Dispensing.
- § The written or typewritten name or initials of the individual who dispensed or administrated the substance on behalf of the dispenser.



Transferring Controlled Substances

What to do if you need to transfer controlled substances to another DEA Registrant.

§ Must use a DEA Form 222 (CI-CII).

21 C.F.R. § 1307.11(a)(1)(iii)

§ Must use a sales invoice for (CIII-CV).

21 C.F.R. § 1307.11(a)(1)(ii)



Transferring Controlled Substances

§ **5% of your yearly total.**

[21 C.F.R. § 1307.11\(a\)\(1\)\(iv\)](#)

§ **If more you must register as a distributor.**

[21 C.F.R. § 1307.11\(b\)](#)



Reports



Theft and Loss

- § Theft or Significant Loss.
- § Not an Inventory Adjustment.
- § Loss (Unexplained Disappearance).
- § Any discovered shortage which the researcher cannot convincingly establish to have been diverted after reasonable review/investigation should generally be considered a loss.



Theft and Loss Reporting

§ **Must report a theft or significant loss to DEA in writing within one business day.**

21 C.F.R. § 1301.76(b)

§ **Must complete a DEA form 106, online, once your investigation is complete.**

21 C.F.R. § 1301.76(b)

§ **Registrants are encouraged to immediately report theft and losses to your local law enforcement and state regulatory agency.**



REPORT OF THEFT OR LOSS OF CONTROLLED SUBSTANCES

Federal Regulations require registrants to submit a detailed report of any theft or loss of Controlled Substances to the Drug Enforcement Administration. Complete page 1, and either page 2 or 3. Make two additional copies of the completed form. Forward the original and duplicate copies to the nearest DEA Office. Retain the triplicate copy for your records. Some states may also require a copy of this report.

OMB APPROVAL
No. 1117-0001
(Expiration Date 9/30/2017)

1. Name and Address of Registrant (include ZIP Code)		2. Phone No. (Include Area Code)	
3. DEA Registration Number		4. Date of Theft or Loss	5. Principal Business of Registrant (Check one) 1 <input type="checkbox"/> Pharmacy 5 <input type="checkbox"/> Distributor 2 <input type="checkbox"/> Practitioner 6 <input type="checkbox"/> Mediation Program 3 <input type="checkbox"/> Manufacturer 7 <input type="checkbox"/> Other (Specify) 4 <input type="checkbox"/> Hospital/Clinic
6. County in which Registrant is Located	7. Was Theft reported to Police? <input type="checkbox"/> Yes <input type="checkbox"/> No	8. Name and Telephone Number of Police Department (Include Area Code)	
9. Number of Thefts or Losses Registrant has Experienced in the Past 24 Months	10. Type of Theft or Loss (Check one and complete items below as appropriate) 1 <input type="checkbox"/> Night Break-in 3 <input type="checkbox"/> Employee Pilferage 5 <input type="checkbox"/> Other (Explain) 2 <input type="checkbox"/> Armed Robbery 4 <input type="checkbox"/> Customer Theft 6 <input type="checkbox"/> Lost in Transit (Complete Item 14)		
11. If Armed Robbery, was Anyone: Killed? <input type="checkbox"/> No <input type="checkbox"/> Yes (How Many) _____ Injured? <input type="checkbox"/> No <input type="checkbox"/> Yes (How Many) _____	12. Purchase value to Registrant of Controlled Substances taken? \$ _____	13. Were any pharmaceuticals or merchandise taken? <input type="checkbox"/> No <input type="checkbox"/> Yes (Est. Value) \$ _____	
14. IF LOST IN TRANSIT, COMPLETE THE FOLLOWING:			
A. Name of Common Carrier	B. Name of Consignee	C. Consignee's DEA Registration Number	
D. Was the carton received by the customer? <input type="checkbox"/> Yes <input type="checkbox"/> No	E. If received, did it appear to be tampered with? <input type="checkbox"/> Yes <input type="checkbox"/> No	F. Have you experienced losses in transit from this same carrier in the past? <input type="checkbox"/> No <input type="checkbox"/> Yes (How Many) _____	
15. What identifying marks, symbols, or price codes were on the labels of these containers that would assist in identifying the products?			
16. If Official Controlled Substance Order Forms (DEA 222) were stolen, give numbers.			
17. What security measures have been taken to prevent future thefts or losses?			

PRIVACY ACT INFORMATION

AUTHORITY: Section 301 of the Controlled Substances Act of 1970 (PL 91-513).

PURPOSE: Report theft or loss of Controlled Substances.

ROUTINE USES: The Controlled Substances Act authorizes the production of special reports required for statistical and analytical purposes. Disclosures of information from this system are made to the following categories of users for the purposes stated:

- A. Other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.
- B. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.

EFFECT: Failure to report theft or loss of controlled substances may result in penalties under Section 402 and 403 of the Controlled Substances Act.

In accordance with the Paperwork Reduction Act of 1995, no person is required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this collection of information is 1117-0001. Public reporting burden for this collection of information is estimated to average 20 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Freedom of Information: Please prominently identify any confidential business information per 29 CFR 16.8(c) and Exemption 4 of the Freedom of Information Act (FOIA). In the event DEA receives a FOIA request to obtain such information, DEA will give written notice to the registrant to obtain such information. DEA will give written notice to the registrant to allow an opportunity to object prior to the release of information.

LIST OF CONTROLLED SUBSTANCES LOST OR STOLEN

Examples

Trade Name of Substance or Preparation	NDC Number	Name of Controlled Substance in Preparation	Dosage Strength	Dosage Form	Total Quantity Lost or Stolen
Desoxyn	00074-3377-01	Methamphetamine Hydrochloride	5 mg	Tablets	300
Demerol	00409-1181-30	Meperidine Hydrochloride	50 mg/ml	Vial	150 ml
Robitussin A-C	00031-8674-25	Codeine Phosphate	2 mg/cc	Liquid	5676 ml
1.					
2.					
3.					
4.					
5.					
6.					
7.					
8.					
9.					
10.					
11.					
12.					
13.					
14.					
15.					
16.					
17.					
18.					
19.					
20.					

Remarks: (Optional)

Express Quantity in Dosage Units, or Milliliters for Liquids



Security

§ Registrants are required to provide effective controls and procedures to guard against theft and diversion of controlled substances.

21 C.F.R. § 1301.71(a)

§ Registrant cannot employ anyone who has a felony drug conviction who will have access to controlled substance, without a DEA approved employment waiver.

21 C.F.R. § 1301.76(a)



Security

§ **Controlled substances listed in CI shall be stored in a locked, substantially constructed cabinet.**

21 C.F.R. § 1301.75(a)

§ **Controlled substances listed in CII-CV shall be stored in a securely locked, substantially constructed cabinet.**

21 C.F.R. § 1301.75(b)



State Regulations

- § **Also consult your state regulating agency for more strict recordkeeping requirements.**
- § **Example - some state boards require records be kept for 7 years.**
- § **Stricter Law Provision.**



Post Questions

1. Who is ultimately responsible for keeping records of controlled substances at the registered location?

- 1. Licensed Practical Nurse**
- 2. Office Manager**
- 3. DEA Registrant**
- 4. Corporation**



Post Questions

- 2. How many controlled substances can a researcher distribute in a calendar year to other dispensers before the practitioner must register as a distributor?**
- A. 40%**
 - B. 20%**
 - C. 60%**
 - D. 5%**



Post Questions

3. If a researcher discovers a theft or significant loss of controlled substances, when must the theft or loss be reported?

- 3. On a DEA Form 106 upon completion of the investigation of the theft or loss.**
- 4. In writing to DEA within 1 business day of discovery of the theft and loss.**
- 5. DEA must be notified upon completion of the local police departments investigations.**
- 6. DEA is not required to be notified.**



*Thank-you for your
time and attention!*

